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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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Mole Med Inc.
c/o Reed Environmental Services
300 Doctors Building
33 East 7th Street
Covington, Kentucky 41011

Attention: Dr. Kenneth Reed:

Subject: Mole Med
EPA File Symbol 64439-R
Your submissions of October 1, November 4, 1992,
January 6, and February 9, 1993
Our letter of March 11, 1992

In our letter of March 11, 1992, we informed Mole Med Inc. that the active ingredient in their product, Castor Oil, was now considered to be a **Biochemical**, which resulted in a reduced set of data requirements that were listed in our letter. We also provided additional information to the Company that would help it to make more successful submissions in the future. Judging from the Company's most recent submissions, we were pleased to see that much of our advice was followed.

On November 18, 1992, the Agency determined that all of the data submitted to it had been properly formatted according to PR Notice 86-5. On November 25, 1992, the Agency determined that the Company had addressed all of the data requirements through submission of actual data or waiver requests and, therefore, was administratively complete.

Scientific Screening of Castor Oil and Mole Med

On December 1, 1992, the Agency sent the Company's submission for scientific screening. During the process the Agency identified Castor Oil as a candidate for status as a **Reduced Risk Pesticide** through a newly evolving process that allowed reductions in data requirements beyond those granted for a Biochemical.

CONCURRENCES							
SYMBOL	H-7505C						
SURNAME	[signature]						
DATE	7/1/93						

*U.S. Government Printing Office: 1992 — 620-856/40672

In order to make a decision, the Agency had to set up a special Ad Hoc Screening Committee for Reducing Risk Pesticides, which met on February 17, 1993, and made recommendations to all five Division Directors of the Office of Pesticide Programs (OPP). In late March the Directors concurred with these recommendations for reducing data requirements, thus concluding the scientific screening of Mole Med. While this extra procedure delayed the completion of the process, it also resulted in elimination of nine toxicological and four fish and wildlife studies, a considerable saving for your client. Assuming that the registrant will use a **USP grade of Castor Oil**, the Agency has waived the studies listed below:

A. Castor Oil (Technical)

1. Acute Oral (151B-10)
2. Acute Dermal (151B-11)
3. Acute Inhalation (151B-12)
4. Primary Eye Irritation (151B-13)
5. Primary Dermal Irritation (151B-14)
6. Hypersensitivity (151B-15)
7. Avian Acute Oral (154-6)
8. Avian Dietary (154-7)
9. Freshwater Fish LC-50 (154-8)
10. Freshwater Invertebrate LC-50 (154-9)

B. Mole Med (End-Use)

11. Acute Dermal (151B-11)
12. Acute Inhalation (151B-12)
13. Hypersensitivity (151B-15)

Scientific Review of Data Supporting Castor Oil and Mole Med

On June 24, 1993, the Agency completed its review of all the submitted data and have provided the results below.

A. Product Chemistry - Castor Oil (Technical)

1. Product Identity (150A-10)

Submit a Confidential Statement of Formula (CSF) for the Castor Oil, itself. Be sure to include your supplier and the name of the grade of the active ingredient, which must be USP or higher. Attached a copy of your source's Product Bulletin.

2. Certified Limits (150A-15)

Indicate the certified limits on your CSF, including any impurities equal to, or greater than, 1%. Indicate how you plan to stabilize the ricinoleic acids in the

technical, the percentage of which can vary from 82% to 95%. Do you plan to blend batches to attain a more uniform product? How will this be accomplished?

B. Product Chemistry - Mole Med (End-Use)

1. Product Identity (150A-10)

✓ Submit a Confidential Statement of Formula (CSF) for the Mole Med. Be sure to include your supplier and the name of the grade of the active ingredient, which must be USP or higher. Indicate the source of your third ingredient.

2. Analytical Method (150A-16)

Submit a copy of the Analytical Method used to measure the amount of active ingredient in your product. Check with your supplier for assistance.

C. Acute Toxicology - Castor Oil (Technical)

The Agency will require no additional data, provided the registrant uses a grade of USP or purer.

D. Acute Toxicology - Mole Med (End-Use)

The Agency found the three acute toxicity studies acceptable, provided the registrant submits information documenting the purity of the active ingredient used in the tests. The Agency will require no additional acute toxicity data for Mole Med, provided the registrant used a grade of USP or purer.

The results of the acute toxicity studies were as follows:

1. Acute Oral (151B-10)	Toxicity Category IV
2. Primary Eye Irritation	Toxicity Category II
3. Primary Dermal Irritation	Toxicity Category III

E. Efficacy (96-8) (End-Use)

The efficacy reports submitted for review (MRID 425489-10) included 1) three form reports and 2) the Tsugawa report. We found both unacceptable for the following reasons:

1. Three Report Forms

On July 10, 1991, the Agency provided Mole Med with a complete copy of our April 30, 1991, efficacy review

so that the Company would have a clear idea why the forms, essentially testimonials, were inadequate to support the claims made for the product.

We were puzzled that the Company had resubmitted these unacceptable studies again and that the author's name, Mr. Eldon Pickett, had been removed from the documents.

2. Tsugawa Report

We found this report unsatisfactory for the following reasons:

a. After the reviewer had read the Report, he decided to try to make contact with the "Tsugawa" facility because he was unfamiliar with it as a Vertebrate Testing Facility and because he had questions about certain details in the Report.

On February 24, 1993, the reviewer telephoned the "Tsugawa" facility and talked with Ms. Uta Crisafulli, the author of the Mole study, as represented by the signature in the Report and by Mr. Pickett's Title Page. The Agency was concerned about several aspects of that conversation.

1) Testing Facility

The reviewer discovered that "Tsugawa", which was represented as a "Laboratory" in Mr. Pickett's title page was not a testing facility but a nursery and greenhouse operation. This was not made clear anywhere in the Report.

2) Study's Author

Further, the reviewer discovered that Ms. Uta Crisafulli had not directed the study even though her name appeared on the Report under the "Tsugawa" letterhead and on Mr. Pickett's Title Page. The real author of the study was Ms. Deborah Anderson, who left Tsugawa six months prior to the telephone conversation.

3) Author's Qualifications

The author is represented in the Report as having a:

"Bachelor of Science
Environmental Studies
College of Natural Resources
Utah State University"

The actual author of the study, which had been conducted a year previously in her own garden, had no training as a scientist.

Ms. Crisafulli said that Mr. Pickett had asked her to sign the report, which was only to be used for advertising and not for supporting EPA registration, because he wanted someone who had at least a B.S. degree to author the study.

4) Study Date

The title page indicated that Tsugawa completed the study on November 21, 1990. The Report provided no dates. Ms. Crisafulli remembered that the study had been completed about a year prior to the telephone conversation (February 1992).

b. The study lacked the details required by the registration guidelines (96-8) to determine if the product was effective.

As indicated in earlier Agency correspondence to the registrant, in order to be considered "acceptable", the researcher must:

a. design a study as a controlled experiment which isolates the effects of your product from other factors which might affect mole activity in treated areas.

b. include monitoring of mole activity before and after the time of application in treated areas and in similarly infested untreated areas nearby.

c. conform to EPA's "GOOD LABORATORY PRACTICE STANDARDS" (40 CFR, Part 160).

d. run studies with moles representing major eastern and western types to claim more than one

species or "moles" in general. We suggest testing the eastern mole (Scalopus aquaticus) and any of the major Scapanus types which occur in the western U.S.

We have suggested in earlier letters to the registrant that he contact biological or agricultural science departments of universities in Indiana and nearby states (e.g, Indiana State University, Purdue University, Michigan State University, Bowling Green State University, etc.) to find qualified individuals who might be interested in running field trials for you at reasonable costs. You might also wish to consult private laboratories.

Before running such studies, you should submit a protocol describing the planned research. If this protocol requires 10 or more acres of land to be treated, you will be required to obtain an Experimental Use Permit (see 40 CFR, Part 172). If your consultant wishes to discuss the protocol while it is under development, he or she may contact Dr. William W. Jacobs of my staff at 703-305-6406.

F. Labeling

1. The "DIRECTIONS FOR USE" portion of the proposed label submitted on December 18, 1991, must be restructured somewhat so that "DIRECTIONS FOR USE" is centered in the column in which it appears, with the "It is a violation . . . labeling" statement being left-justified and appearing directly below "DIRECTIONS FOR USE." The subheading "USE RESTRICTIONS" must be left-justified. A subheading entitled "MIXING DIRECTIONS" also is needed.

2. The amended "DIRECTIONS FOR USE" should appear as indicated below.

"DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

USE RESTRICTIONS: For repelling eastern moles and Townsend's moles from lawns.

MIXING DIRECTIONS: Mix with water at a rate of one ounce of MOLE-MED per gallon of water. Use the DILUTION TABLE below to determine the amount of mixture to prepare for the area that you intend to treat. SHAKE MOLE-MED CONTAINER WELL BEFORE MIXING.

DILUTION TABLE

Amount of MOLE MED	Amount of Water	Area to be Covered
1 Oz.	1 Gal.	312 sq. ft.
2 Oz.	2 Gal.	624 sq. ft.
16 Oz.	16 Gal.	5,000 sq. ft.
32 Oz.	32 Gal.	10,000 sq. ft.

LOCATING MOLES: The presence of moles may be indicated by a network of surface ridges in the turf or by a series of conical mounds of earth pushed up from deep burrows. Treated all areas which show signs of moles' presence.

APPLICATION DIRECTIONS: Apply MOLE-MED with a hand-held sprayer or sprinkling can to entire area that is to be rid of moles or protected from moles. Cover treated area thoroughly with mixture of MOLE-MED and water. After treatment, water treated area with hose or sprinkler for an additional 25 minutes. If soil is dry, water area thoroughly prior to treatment. If heavy rains occur shortly after treatment, application may have to be repeated.

3. Labels proposed for this product in the past have included claims of absolute effectiveness and statements to the effect that the product is "safe" or somehow ecologically appropriate. Such statements render pesticide products "misbranded" when they appear on labeling or any printed matter which accompanies the product in commerce. In addition do not use such statements in product advertising.

We hope that you have found this letter helpful. If you have questions about this letter, please contact Mr. Dan Peacock at 703-305-5407 or 305-6600.

Sincerely yours,

Robert A. Forrest
Product Manager (14)
Insecticide-Rodenticide Branch
Registration Division (H7504C)

cc 1. Mole Med Inc.
204 5th Street
Aurora, IN 47001

2. Lane Ralph
c/o Senator Lugar's Office
1180 Market Tower
10 West Market Street
Indianapolis, IN 46204-2964

Peacock WP#2:A\:64439JN.R:305-5407/-6600:7/1/93

Copies faxed to Mole Med 812-537-4464
Kenneth Reed 606-431-6228